

**Health Information Technology Standards Committee**  
**Final**  
**Summary of the August 30, 2010, Meeting**

## **KEY TOPICS**

### **1. Call to Order**

Judy Sparrow, Office of the National Coordinator (ONC), welcomed participants to the 16th meeting of the HIT Standards Committee (HITSC), which was being conducted virtually. She reminded the participants that this was a Federal Advisory Committee meeting, with an opportunity for the public to make comments. Following her opening remarks, she conducted roll call.

### **2. Opening Remarks and Review of the Agenda**

HITSC Chair Jonathan Perlin also welcomed participants to the meeting and reviewed the agenda. In his opening remarks, Committee Co-Chair John Halamka noted that the final rule still stands up well after 2 months of intense inspection. There is one mistake in the rule—the incorrect version of the syndromic surveillance implementation guide was referenced. He asked that any Committee members who identify or learn of any inconsistencies or questions about the final rule to forward these to him, and he will collect and deliver this information.

**Action Item #1:** Minutes from the last HITSC meeting, held on July 28, 2010, were approved by consensus.

### **3. Enrollment Workgroup Update**

Enrollment Workgroup Co-Chair Sam Karp updated the Committee on the progress of the Enrollment Workgroup and presented final recommendations for approval. During its last meeting (held the week prior to this meeting), the HIT Policy Committee (HITPC) reviewed and approved these recommendations.

The Enrollment Workgroup has held five meetings and established four tiger teams to develop these recommendations. Doug Fridsma of ONC led an internal team of staff and consultants to examine the standards development at the state level. The Workgroup held a series of public hearings and maintained a blog, from which it received public input.

Sam Karp presented the Workgroup's first recommendation:

- Recommendation 1.1: We recommend that federal and state entities administering health and human services programs use the National Information Exchange Model (NIEM) guidelines to develop, disseminate, and support standards and processes that enable the consistent, efficient, and transparent exchange of data elements between programs and states.

In response to a question from Wes Rishel, Sam Karp explained that the group's review of the data elements has led it to believe that it is possible to conduct verification without states having to change their systems, provided that the output of the 10-12 core data elements conforms with NIEM exchange guidelines. Doug Fridsma noted that there was fairly good consistency across all of the agencies with regard to collecting the required data. Some of the variability that was identified related to business rules.

It was noted that there will be local autonomy for deciding how to use this system to exchange.

The next set of Enrollment Workgroup recommendations were as follows:

- Recommendation 2.1: We recommend that federal agencies required by Section 1411 of the Affordable Care Act (ACA) to share data with states and other entities for verification of an individual's initial eligibility, re-certification, and change in circumstances for ACA health insurance coverage options (including Medicaid and CHIP), use a set of standardized Web services that could also be used to support such eligibility determinations in other health and human services programs such as SNAP and TANF.
  - To accomplish this recommendation, federal and state agencies should provide data by individual, as opposed to household, to ensure the data can be used in a consumer-mediated approach.
- Recommendation 2.2: We recommend development of a federal reference software model, implementing standards for obtaining verification of an individual's initial eligibility, re-certification and change in circumstances information from federal and state agencies, to ensure a consistent, cost-effective, and streamlined approach across programs, states, and community partners.
  - The initial build of this toolset should include interfaces to the federal agencies referenced in Recommendation 2.1. In order to ensure comprehensive and timely verification, additional interfaces to other Federal, State or other widely-available data sources and tools should be added, including the National Directory of New Hires, the Electronic Verification of Vital Events Record (EVVE) system, State Income and Eligibility Verification (IEVS) systems, Public Assistance Reporting Information System (PARIS), and the U.S. Postal Service Address Standardization API tool.

In discussion, Wes Rishel noted that a key aspect of this tooling is that it must work with legacy systems. Most of what is done now is based on JAVA, .net, and other modern systems, and it will be important for the Committee to determine how to represent the legacy system implementers. Sam Karp noted that new systems developed in the large states potentially will have the ability to more easily interface with the exchange being discussed.

Workgroup Chair Aneesh Chopra then presented the next set of recommendations:

- Recommendation 3.1: Federal and state agencies should express business rules using a consistent, technology-neutral standard (e.g., OMG's SBVR, WC3's RIF, etc.). Upon

identification of a consistent standard, federal and state agencies should clearly and unambiguously express their business rules (outside of the transactional systems).

- Recommendation 3.2: To allow for the open and collaborative exchange of information and innovation, we recommend that the federal government maintain a repository of business rules needed to administer ACA health insurance programs coverage options (including Medicaid and CHIP), which may include an open source forum for documenting and displaying eligibility, entitlement and enrollment business rules to developers who build systems and the public in standards-based and human-readable formats.
  - To allow for seamless integration of all health and human services programs, business rules for other health and human services programs such as SNAP and TANF should be added to the repository over time.

The Committee's discussion on these recommendations included the following points:

- David McCallie noted that if the NIEM is managing the data element issue in a different format or system, some of these elements do not have tools available as of yet. This could lead to multiple independent repositories of information. Aneesh Chopra acknowledged that this policy issue demonstrates the fact that a common language for this has not yet been developed. Doug Fridsma noted that the NIEM process works well with data, but it does not capture such behavioral aspects as business rules and what happens with the data. Work has been ongoing to expand the functionality of the NIEM process to describe the service and behavioral aspects for which the rules are going to be a part.
- Cris Ross noted that the Business Rules Tiger Team has discussed this issue at length, and the core view is that business rules cannot exist abstract from a data domain. The expectation is that the business rules would have a clear cross-representation to the data model. However, if the data, the program rules, and the deployment were consistent across states, then there would be no need for business rules. The tiger team was trying to document a set of rules once for deployment, such that those rules can be used everywhere.
- Wes Rishel said that any process that leads an organization to state their business rules in a way that others can understand would be beneficial.
- David McCallie explained that if the goal is to develop a system that is deployable to multiple environments, then expressing the rules in terms of deployment would mean there would be almost infinite variations when program differences and state-to-state differences are layered on.

Aneesh Chopra presented the Enrollment Workgroup's fourth series of recommendations:

- Recommendation 4.1: We recommend using existing Health Insurance Portability and Accountability Act (HIPAA) standards (e.g., 834, 270, 271) to facilitate transfer of applicant eligibility, enrollment, and disenrollment information between ACA health insurance programs, coverage options (including Medicaid and CHIP), public/private health plans, and other health and human service programs such as SNAP and TANF.

- Recommendation 4.2: We recommend further investigation of existing standards to acknowledge a health plan's receipt of an HIPAA 834 transaction and, if necessary, development of new standards.

Nancy Orvis asked whether there has been a resolution of the issue of key code sets on identifying a person. Farzad Mostashari replied that this issue has not yet been completely resolved. Nancy Orvis noted that this represents a significant challenge; if there is still no compatibility on what the set will be, then some of the hardest work is still to be done. There cannot be common business rules if there is not a common understanding of what the data is. Therefore, she suggested, Recommendation 4.2 needs to be stronger than it is, and needs to push for more work to harmonize the code sets.

Aneesh Chopra then presented the Workgroup's final set of recommendations, as follows:

- Recommendation 5.1: We recommend that consumers have: (1) timely, electronic access to their eligibility and enrollment data in a format they can use and reuse; (2) knowledge of how their eligibility and enrollment information will be used, including sharing across programs to facilitate additional enrollments, and to the extent practicable, control over such uses; and (3) the ability to request a correction and/or update to such data.
  - This recommendation builds upon the Health Information Technology for Economic and Clinical Health (HITECH) Act, which gave consumers the right to obtain an electronic copy of their protected health information from HIPAA-covered entities, including health plans and clearinghouses. Additional investigation into format and content of such disclosures is needed.
- Recommendation 5.2: We recommend that the consumer's ability to designate third-party access be as specific as feasible regarding authorization to data (e.g., read-only, write-only, read/write, or read/write/edit), access to data types, access to functions, role permissions, and ability to further designate third parties. If third-party access is allowed, access should be:
  - Subject to the granting of separate authentication and/or login processes for third parties;
  - Tracked in immutable audit logs designating each specific proxy access and major activities; and
  - Time-limited and easily revocable.
- Recommendation 5.3: We recommend that state or other entities administering health and human services programs implement strong security safeguards to ensure the privacy and security of personally identifiable information. Specifically, we recommend the following safeguards:
  - Data in motion should be encrypted. Valid encryption processes for data in motion are those which comply, as appropriate, with NIST SP 800-52, 800-77, or 800-113, or others which are Federal Information Processing Standards (FIPS) 140-2 validated.
  - Automated eligibility systems should have the capability to:
    - Record actions related to the PII provided for determining eligibility. The date, time, client identification, and user identification must be recorded when

electronic eligibility information is created, modified, deleted, or printed; and an indication of which action(s) occurred must also be recorded.

- Generate audit logs. Enable a user to generate an audit log for a specific time period and to sort entries in the audit log.

In Committee discussion, the following points were raised:

- Kevin Hutchinson asked for clarification on the definition of a third party as referenced in Recommendation 5.2. Would a provider of medical care be considered a third party? Aneesh Chopra provided an example of the type of entity that these recommendations are considering. The example was a non-profit organization advocating on behalf of a provider to make sure that it is getting all of the benefits it is entitled to. The intent of Recommendation 5.2 is that this arrangement be separately maintained, versus having the organization simply use the provider's log-in and password.
- If the Workgroup's recommendations are approved, the group will follow up with the supporting material that is going to be provided in the appendices. The deadline for completing this work is September 17, to move the material through the internal clearance process to determine whether the recommendations will be accepted in full or in part and then promulgated by the Secretary for states to use. The Workgroup recognizes that it is far from being able to give the definitive implementation guidance that they would like to provide.
- In response to a question about the core data elements, Farzad Mostashari pointed Committee members to Appendix B, which discusses this topic.
- Wes Rishel suggested a line edit to Recommendation 3.1. After the first sentence, he suggested the wording, "consistent with data standards developed under other recommendations."
- Dixie Baker suggesting adding a reference to Fair Information Practices in Recommendation 5.1
- Carol Diamond commented that it would be beneficial if all of the privacy and security recommendations were organized within the context of the ONC framework (i.e., the Fair Information Practices).
- Farzad Mostashari said that, in terms of practical edits, this might translate to having a header section for the privacy and security recommendations that discusses the overall privacy and security framework and the Fair Information Practices, prior to the specific recommendations.

**Action Item #2:** The recommendations of the Enrollment Workgroup were approved by consensus, with line edits as described (i.e., adding "consistent with data standards developed under other recommendations"

to the end of the first sentence in Recommendation 3.1, and adding a reference to Fair Information Practices in Recommendation 5.1).

#### **4. Privacy and Security Tiger Team Recommendations**

Deven McGraw and Paul Eggerman presented the Privacy and Security Tiger Team's recommendations to the Committee, noting that last week the HITPC accepted these without modifications. The team has been presenting various components of these recommendations to the HITSC during previous meetings, and Committee member feedback has been incorporated into the final product. The Committee received the team's letter outlining the complete set of recommendations. Some of the more salient recommendations were discussed during the meeting.

The team's overarching recommendation is that all entities involved in health information exchange—including providers (individual and institutional) and third-party service providers such as health information organizations (HIOs) and other intermediaries—should follow the full complement of Fair Information Practices when handling personally identifiable health information. Each set of recommendations is mapped to applicable Fair Information Practices Principles.

Deven McGraw and Paul Eggerman presented recommendations dealing with intermediaries and third-party service providers, the trust framework to allow exchange among providers for the purpose of treating patients, triggers for additional consent, meaningful consent attributes, consent implementation guidance, and provider choice about participation in exchange models.

In discussion, the following points were made:

- On the subject of granularity, Carol Diamond clarified that the team's previous recommendations were not necessarily "all or nothing." If the provider is in control of the exchange, then the provider and the patient can share some control over which information is shared. This relates to what technology is used in the sharing.
- John Halamka proposed an operational example involving e-prescribing. Checking a patient's eligibility is a non-persistent transaction: nothing is deposited in a repository. There is nothing persistent in a check against the formulary. Then, there is a drug interaction check, which would imply that the e-prescribing entity had a list of previous transactions. Medication reconciliation is part of meaningful use, and that crosses the line into persistence. The challenge here is the notion of achieving consent. There is participation in the transaction but not the maintenance of history.
- Kevin Hutchinson asked about which model would apply to e-prescribing, an HIO model or a direct exchange model. The information used is not aggregated at a single point and then delivered. Paul Eggerman explained that the trigger for consent would be a place where the medication profile from multiple providers is kept. If the information can be obtained from other sources through direct exchange, then there would be no trigger. David McCallie

added that it is an issue of information control, and not where the information sits. The issue is what controls are in place to guarantee that the access is appropriate.

- Wes Rishel referenced a previous Veterans Health Administration hearing and explained that one theme that arose from those discussions was that there is a tradeoff between how granular the consent is and how difficult it is to explain options to the patient. This is part of the difference between what is technically possible and what is practical.
- Jonathan Perlin acknowledged that this is a complex dialog, including new forums that defy traditional categorization. Additional work may be needed in standards classification of the entities that are involved in these complex relationships.

## **5. Standards and Interoperability Framework**

John Halamka noted that a series of Requests for Proposals (RFPs) were issued by the ONC, and this Committee will provide some oversight for the work of the contract winners.

Doug Fridsma said that as they plan their work going forward, continued emphasis on standardization and need to move towards increasingly computational specification implementation are needed. Also, a mechanism so that standards can be manipulated by tools is required. These tools need to be stored in repositories that can be used by those interested in information exchange. Rather than a set of descriptions that would be difficult to harmonize, it is important that they are linked from inception all the way through certification, implementation specifications, and standards that can be tested for certification. This necessitates involving the National Institute of Standards and Technology (NIST) and other entities early in the process.

The Standards and Interoperability (S&I) Framework is the framework by which the ONC will manage this work, to promote interoperability and meaningful use. The S&I Framework is not intended to develop new standards in and of itself, but it will help the ONC to work with health care organizations throughout the health care community.

In a series of slides, Doug Fridsma explained the S&I Framework, and reviewed the following characterizations of the Framework:

- Managing the lifecycle: There needs to be a controlled way to manage all the activities within the standards and interoperability activities from identification of a needed capability to implementation and operations.
- Reuse: Standards development and harmonization efforts need to accommodate multiple stakeholders and business scenarios so as to ensure reuse across many communities.
- Semantic discipline: The work products need to be developed in a way to ensure computability and traceability throughout the entire lifecycle.
- Human consensus: Achieving human consensus is a prerequisite for computable interoperability

Within a few weeks, all of the contracts will be in place. Doug Fridsma showed a timeline illustrating the contracts supporting the network. Contractors awarded so far include Deloitte, Lockheed, and Stanley. The government will serve as a platform to support the work, creating a neutral ground.

As part of this effort, there is a need to leverage the HIT community, to take professional organizations, government agencies, and standards organizations, and ensure that all of their work comes down to a harmonized set of standards and implementable specifications. The goal is to solve real problems around meaningful use. The contractors will develop content exchange standards, transportation standards, nomenclature and value sets, and throughout the process will ensure that there are privacy and security standards to support the implementation specifications.

The S&I Framework will provide coordination across strategic, operational, and technical issues. A top-down approach is needed to establish goals and an acceptance process. A bottom-up method is necessary to involve the standards community.

Committee discussion followed, during which these points were raised:

- John Halamka said that previous uses of NIEM framework have been in different kinds of environments. He raised the possibility that this strategy may not fit into the health care framework, with its existing infrastructures and platforms. Doug Fridsma acknowledged that vigilant monitoring will be necessary. The process that NIEM undergoes to develop data specifications is similar to the processes within other standards organizations, including CDIP, HL7, and also the National Cancer Institute.
- Stan Huff commented that he likes the overall approach and its collaborative nature. He indicated that he did not have a clear picture of how the interoperability framework interacts with the formal processes in the other standards development organizations. When a new standard is needed, it may be possible to rapidly make a new prototype, but does that need to go to ballot somewhere? Will existing standards organizations be used for this, or will ONC become an “uber-standards” organization?
- Doug Fridsma explained that the goal is to coordinate across all of the different standards-development organizations (SDOs). The ONC will not serve as an “uber-standards” organization, and it will not replace the work of SDOs. When impossibly tight timeframes for standards development occur, it would be useful to have an organization that could come up with a potential standard and then develop the transfer method, content, vocabulary, etc. Then, that whole package can be handed to SDOs to make sure that they are appropriately balloted. As it relates to this work, the government’s job is not to create standards, but to identify the need for them.
- Wes Rishel described a continuum, between SDOs and profiler and enforcer organizations. The current NHIN Direct operation, for example, is a profiler. It did not define new standards; rather, it decided how to pick among standards and create interfaces between them. The Healthcare Information Technology Standards Panel (HITSP) is a profiler. One of the advantages of the NIEM approach is that it can solve some of the problems that



profiler organizations can have, but it can only do so if it acquires the right intellectual property from the SDOs. He suggested that there be some sort of visioning process looking downstream for standards that will be needed when there is time to actually use the benefits of an SDO consensus process to obtain a broad perspective on the requirements and possible solutions.

- Doug Fridsma acknowledged that one unresolved issue involves intellectual property and engagement with SDOs. He hopes that the Committee can provide some guidance in this area. If solving problems requires multiple different groups to be able to come together and bring their expertise to the table, it will be important for there to be a comprehensive policy regarding the engagement of SDOs. They must be able to contribute to those packages and still have business models that are able to support the work in which they are engaged.
- Nancy Orvis pointed to the business model and financing the maintenance of standards as the underlying issue. For those who are trying to help as organizational providers or as government agencies, it can be extremely complicated to determine all of the different levels to which resources need to be assigned.
- Carol Diamond suggested that it is time to operationalize this process. She reminded the Committee that she has often discussed the interplay between policy and technology in the formation of standards and implementation guides. Policy needs to be present in a visible and required manner. Her sense now is that because there has been some progress on information exchange, and because the ONC framework is in place, that those policies have to be a part of the contracts that are active. They need to be integrated into the approach in a very operational way. She commented that it would be detrimental if a situation arose in which the implementation guide or other items have to be reworked, or the policy objectives cannot be fulfilled, because the technical work was done out of sync.
- Dixie Baker asked whether milestones and metrics have been established for measuring the process. Doug Fridsma explained that this is one of the first charges of those who are working on the contracts. Most of the contracts have been awarded within the last 3 weeks, and there is still time to submit feedback and suggestions.

## **6. Vocabulary Task Force Update**

Vocabulary Task Force Chair Jamie Ferguson shared information about the upcoming September 1 hearing that will be held by the Vocabulary Task Force. He explained that in March, the Task Force held public hearings to answer questions about the national governance of terminology and subsets related to meaningful use. A set of resultant recommendations was forwarded to the National Coordinator. One of the themes that arose during those hearings was the desire for “one-stop shopping,” to make it easy for implementers to have access to the required vocabulary value sets and subsets. Therefore, the overall framing of the September 1 hearing is to gain input and understand what would constitute the right set of requirements for infrastructure that would provide this one-stop shopping.

Which of these requirements would have the highest priority for achieving meaningful use? Other overarching questions guiding the hearing include: what do you think a one-stop shop means? Which requirements are urgent? What would be a staged approach to creating such an environment? Each of the 23 panelists will be asked a series of questions relating to their unique experiences and perspectives. The panelists are divided into four sets: (1) value set developers; (2) end users, with a focus on clinicians, hospitals, and medical centers; (3) EHR vendors; and (4) vendors, developers, and implementers of technical services from the commercial and government sectors.

Jamie Ferguson also noted that the Vocabulary Task Force's parent group, the Clinical Operations Workgroup, has been in discussions with Aneesh Chopra regarding the need for better understanding in terms of standards for remote sensing. Examples include collecting data on vital statistics in hospital and clinical settings and remote sensor data for home and other remote settings. The Clinical Operations Workgroup will plan a hearing on this topic.

## **7. Implementation Workgroup Update**

Implementation Workgroup Chair Judy Murphy noted that the group is in transition. The Workgroup is developing a new member list and expanding its membership to draw in additional experts who have implementation experience. The Implementation Workgroup has rewritten its broad charge as follows: "To bring forward real-world implementation experience into the HIT Standards Committee recommendations, with emphasis on strategies to accelerate the adoption of proposed standards or mitigate barriers, if any."

The Implementation Workgroup's next meeting is scheduled for September 15 and will include an orientation for new members.

## **8. Public Comment**

David Tau of Siemen explained that his understanding is that the document being prepared by the ONC to tie together the S&I Framework will explain how the public and vendors can be engaged. He asked when that document will be made available. Doug Fridsma explained that it will be difficult to finalize this until all of the contracts have been awarded.

## **SUMMARY OF ACTION ITEMS**

**Action Item #1:** Minutes from the last HITSC meeting, held on July 28, 2010, were approved by consensus.

**Action Item #2:** The recommendations of the Enrollment Workgroup were approved by consensus, with line edits as described (i.e., adding "consistent with data standards developed under other recommendations" to the end of the first sentence in Recommendation 3.1, and adding a reference to Fair Information Practices in Recommendation 5.1).